



6111 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 DEax [561) 995-5188

March 18, 2000

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. (Sundown) located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Thompson and Sundown brand names bearing the following statement(s) on the label and/or in the labeling:

<u>Lycopene 5000 mcg (Thompson)</u>: Lycopene provides superior antioxidant protection that promotes healthy cell structure and aids against oxidative cell damage.

Lycopene (Sundown): For healthy prostate function and cellular protection. Lycopene, a carotenoid primarily found in ripe, red tomatoes, promotes healthy prostate function. [It] plays an important role in the body's defense against free radicals.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Vice President of Regulatory Affairs

Webrah Shun Ander

and Assistant General Counsel

Enclosure